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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,970	09/22/2003	Martin Eigenthaler	5281.1666-01	4961

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,970

Applicant(s)

EIGENTHALER ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/22/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/530,864.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. The preliminary amendment filed 22 September 2003 has been received. Claims 1-24 have been canceled. Claims 25-42 have been added and are pending.

Claim Rejections - 35 USC § 112, second paragraph

2. Claims 30, 36 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims recite "natural" fragments of a monoclonal antibody. This is indefinite since monoclonal antibodies, per se, are not "natural". In other words, they do not naturally occur in a biological system but must be manufactured.

Claim Rejections - 35 USC § 112, first paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 25-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the monoclonal antibody 16C2 that binds VASP as antigen when VASP is present in the phosphorylated form, does not reasonably provide enablement for any other antigen binding protein nor any other monoclonal antibody which recognizes VASP as antigen when VASP is present in the phosphorylated form. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification, specifically at pages 3, 7, 8, 11, 12, discloses a hybridoma cell line 16C2 producing the monoclonal antibody 16C2 that binds phosphorylated VASP. Specifically when VASP is phosphorylated at serine position 239. Nowhere in the specification is there a teaching of any other hybridoma producing any other protein or monoclonal antibody that will bind phosphorylated VASP. Although the specification briefly mentioned that monoclonal antibodies which recognize phosphoserine 157 and phosphothreonine 278 VASP can be isolated using the procedures disclosed for Mab 16C2, it does not give any other detail regarding such a monoclonal antibody nor any characteristics of the hybridoma capable of producing the claimed antibody.

The specification lacks any description of the claimed hybridoma producing the claimed monoclonal antibody and because the deposit of one particular monoclonal antibody (i.e. 16C2), does not enable a monoclonal antibody which may have binding properties that are similar, or which may bind the same antigen because replication of a specific monoclonal antibody is an unpredictable event. Therefore, the claims are not enabled by the specification as filed.

Because the claimed monoclonal antibody has not been properly described and because it is well recognize in the prior art that microheterogeneities (see Harris et al) are common the production of complex glycoprotein such as monoclonal antibodies, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

Therefore, lacking specific teachings in the specification as to any other VASP binding monoclonal antibodies, one skilled in the art cannot make and use the invention as claimed.

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Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 25, 27, 29-31, 33, 35-37, 39, 41 and 42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Abel et al (European Journal of Cell Biology. 1996 – abstract only).

Abel discloses VASP phosphorylation/dephosphorylation monoclonal antibodies. Abel states that a monoclonal antibody was found to inhibit phosphorylation and desphosphorylation of VASP at Ser¹⁵⁷. See the abstract.

Even though Abel does not specifically disclose a kit comprising the antibody, the instant kit is nothing more than an antigen binding protein which is taught by Abel.

Conclusion


7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
9/10/04